UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	**MDL No. 2804**
THIS DOCUMENT RELATES TO:	**Case No. 17-md-2804**
Track Three	**Judge Dan Aaron Polster**

PHARMACY DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE CARMEN CATIZONE

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INTRODUCTION

Plaintiffs' Opposition confirms that Carmen Catizone's expert opinions should be excluded entirely or, at a minimum, significantly limited.

The Opposition is premised on a logical fallacy. Because they intend to prove their case through "aggregate evidence," Opp'n 13 (noting "this Court's own previous rulings that Plaintiffs are entitled to present their case through aggregate evidence"), Plaintiffs reason that any evidence they label "aggregate evidence" must necessarily be reliable, admissible, and sufficient to carry their burden of proof. Not so—merely labeling something "aggregate evidence" does not allow Plaintiffs to evade the ordinary requirements of admissibility, including the requirements of Rule 702 that expert testimony be helpful to the jury, based on sufficient facts and data, the product of reliable principles and methods, and reliably applied to the facts of the case. Catizone's proposed testimony fails these requirements.

ARGUMENT

I. Plaintiffs Do Not Deny that Catizone's Methodology Is Untested and Fail to Demonstrate Its Reliability.

As Pharmacy Defendants explain in their motion, Catizone's methodology for identifying prescriptions that are subject to red flags—which mechanistically and unthinkingly applies bright-line tests, regardless of context or any other information about the prescription or prescriber—is unreliable.

In response, Plaintiffs mischaracterize both Pharmacy Defendants' arguments and their own expert's testimony. Plaintiffs incorrectly state that Pharmacy Defendants' "main argument against the admissibility" concerns "a single criterion." Opp'n 4. In truth, Pharmacy Defendants focused on that single criterion merely as one example of the arbitrary and irrational nature of Catizone's methodology.

"Distance" was a perfect example because Catizone recognized that other pharmacists might properly—in their "professional and independent judgment"—apply his tests in different ways or apply different tests altogether. *See* Catizone Tr. 399:15–16, June 16, 2021 ("Catizone II Tr.") (admitting that another pharmacist might properly "make a determination that 30 miles or 20 miles may not be a red flag").[1] Plaintiffs mischaracterize this testimony by describing Catizone's concession as a "[d]isagreement . . . about a particular standard of care." Opp'n 8. That is false—Catizone did not testify that although other pharmacists might disagree, in his view, the proper standard of care required every pharmacist to use his 25-mile test. Catizone II Tr. 399:15–16. To the contrary, he admitted that the standard of care did *not* require every pharmacist to use the same mechanical test and that pharmacists could properly use their "professional and independent judgment" to apply different tests. That is, he picked 25 miles as a "safe parameter," Catizone II Tr. 399:12–13, but never testified that the standard of care required every pharmacist to use this test.

Catizone had to pick an arbitrary distance in order for Plaintiffs to attempt to identify red flags mechanistically, but he was unwilling to testify that this standard was required to be applied

[1] The transcripts from Mr. Catizone's deposition are filed on the docket at ECF No. 3859.

to all pharmacists. The same arbitrariness is true for many of his other red flag criteria.[2] This renders Catizone's opinion unreliable and subject to exclusion.

Indeed, Catizone freely admitted at his deposition that his methodology erroneously flags some prescriptions that are not "actually red flags," just as Defendants' Motion explains. Catizone II Tr. 509:23–510:1 ("[H]ow many of those were actually red flags, I don't have that information[.]"); *see also* Catizone I Tr. 218:14–19 (agreeing that "there are going to be some prescriptions that were flagged under these flags that fall within these exceptions" and thus are not actually red flags). Plaintiffs' argument—that Catizone "catalog[ued] how many opioid prescriptions . . . exhibited 'red flags,'" Opp'n 3—conflicts with Catizone's actual testimony, which admitted that among the prescriptions his mechanistic methodology flagged, he does not know how many of them *actually* involved red flags.

Mr. Catizone has made no attempt to test his methodology. In fact, Catizone has taken the position that he need not test certain of his key assumptions, including whether any properly "red-flagged" prescriptions were actually diverted at a rate higher than other prescriptions, because he can assume as much by virtue of there being "too many opioids." Catizone I Tr. 174:3–22, 175:4–23, 175:25–176:20. Nor has his methodology ever been used before this litigation. His methodology was created out of whole cloth as a litigation-driven attempt to bolster Plaintiffs'

[2] Catizone Tr. 220:18–223:5, June 15, 2021 ("Catizone I Tr.") (overlapping prescriptions may not be illegitimate or diverted); *id.* at 231:14–232:8 ("[m]ultiple prescribing . . . could be indicative of poorly managed care" rather than illegitimate scripts); *id.* at 236:21–237:4 (recognizing that prescriptions for a combination of an opioid and a benzodiazepine may be legitimate); *id.* at 243:7–249:3 (agreeing that excessive dispensing red flag used 200 MME per day before 2018 even though 200 MME was considered a safe dosage and that some conditions, such as cancer and hospice care, require higher doses of opioids and higher MMEs); *id.* at 249:8–21 (acknowledging that he does not know the basis for the one-hour metric for pattern prescribing because McCann unilaterally implemented that metric); *id.* at 250:19–256:11 (agreeing that pattern prescribing flag captures patients who had prescriptions written on different days but happened to fill them on the same day and that, as to red flag 13 for four or more patients on the same day with the same prescription, pharmacist would not know of red flag for first three patients but all four scripts flagged under his analysis); *id.* at 257:15–258:16 (agreeing that red flag for a 210-day supply in a six-month period captures cancer and hospice patients and legitimate chronic pain); *id.* at 261:22–262:7 (recognizing that patients may pay in cash if they lack insurance, but his metric did not isolate patients with insurance who paid cash)

claims. It should be excluded. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593–94 (1993) (noting the importance of the methodology's "known or potential rate of error" and "whether it can be (and has been) tested").

II. Catizone Should Not be Permitted to Testify that Flagged Prescriptions Were Not Written for a Legitimate Medical Purpose.

With respect to Catizone's testimony that flagged prescriptions were not written for a legitimate medical purpose, Plaintiffs' response is difficult to understand. Pharmacy Defendants quoted (at 4–5) unambiguous testimony from Catizone's deposition in which he admitted that "just because a prescription flags under one of [his] 16 red flags . . . **does not mean that it was written for an illegitimate medical purpose**." Catizone I Tr. 167:3–7, 167:20–24 (emphasis added); *accord* Catizone II Tr. 418:10–19; Catizone I Tr. 212:16–20, 238:14–18.

Plaintiffs have no response to this testimony. They ignore it entirely. Opp'n 11–14. They fail to advance any cognizable argument in this portion of the Opposition, and it is unclear whether Plaintiffs even seek to offer this testimony. *See id.* at 11 ("To be clear, however, Mr. Catizone does not intend to testify about specific, individual prescriptions that were not written for a legitimate medical purpose.").

Given this uncertainty and Catizone's unambiguous testimony at his deposition about the limits of his methodology, if Catizone is permitted to testify, this Court should make clear that he cannot testify (and Plaintiffs cannot argue) that his methodology identifies any prescriptions that were "not written for a legitimate medical purpose."

III. Plaintiffs Fail to Demonstrate that Catizone's Opinions About Correlations Between Flagged Prescriptions and Diversion Is Reliable.

Nor do Plaintiffs have any defense of Catizone's speculation about a link between flagged prescriptions and diversion. At his deposition, Catizone conceded that the most common form of diversion—"approximately 70% of people reporting nonmedical use of prescription medications,

including opioid pain relievers"—resulted from prescriptions that would not be flagged by his reg-flag methodology. Catizone I Tr. 172:10–20 ("[N]one of the red flags identify that activity."); *see also id.* 173: 15–174:1.

Even assuming that Catizone can reliably testify that "Defendants' dispensing practices were imprudent, and in the aggregate, resulted in more opioids being dispensed than should have been dispensed under the circumstances," Opp'n 16–17, Plaintiffs identify no reliable basis for Catizone making the crucial assumption that these purportedly overprescribed opioids were *diverted*.

Defendants do not deny that, in theory, a properly qualified expert could apply a reliable basis to opine about a link between certain prescriptions and diversion. *See id.* at 14 (arguing that an expert could "make conclusions about the consequences of the sheer magnitude of 'red flag' prescriptions"); *id.* at 15 (arguing that an expert's causation opinion can ignore alternative causes); *id.* at 16 (arguing that an expert's causation opinion can be "premised on recognized sources of harm that, according to the expert's experience, increase the likelihood of materializing into damage"). None of this is disputed.

The problem, however, is that Catizone has not actually done so. He identifies nothing—not in his experience, background, methodology, or anything else—that qualifies him to identify a statistical link between prescriptions flagged by his mechanistic methodology (including the false positives) and the rate of opioid diversion, or entitles him to opine that the opioids dispensed pursuant to flagged prescriptions were diverted at a higher rate than other opioids.

Pharmacy Defendants are not challenging testimony that opioids can be diverted. To the extent Catizone intends to specifically opine that a certain number of prescriptions actually were diverted (or diverted at a higher rate than other prescriptions), however, he must have some basis

for saying so other than his *ipse dixit*. This is an important opinion, which Catizone and Plaintiffs have deliberately avoided testing, designed to help Plaintiffs prove their case entirely through an expert's word alone, without conducting any real analysis of diversion rates and causes and whether their "flagging" methodology successfully identifies prescriptions that were diverted.

Even if Catizone could provide a general causation opinion that prescriptions flagged by his methodology could be the subject of "diversion or abuse or a problem," he has no expertise or factual basis to express a specific causation opinion that "a significant number of those prescriptions *were* diverted." Mot. 5 (emphasis added).

Admitting this testimony would be prejudicial error and would necessitate a new trial. Plaintiffs have not presented reliable evidence of a link between Catizone's methodology and diversion, and Catizone's unreliable opinion should be excluded.

CONCLUSION

For these reasons, Defendants respectfully renew their request that this Court exclude or limit the testimony of Catizone.

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Respectfully submitted,

/s/ Eric R. Delinsky

Alexandra W. Miller
Eric R. Delinsky
ZUCKERMAN SPAEDER LLP
1800 M Street, NW
Suite 1000
Washington, DC 20036
Phone: (202) 778-1800
E-mail: smiller@zuckerman.com
E-mail: edelinsky@zuckerman.com

Attorneys for CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS Pharmacy, Inc., CVS TN Distribution, L.L.C., and Ohio CVS Stores, L.L.C.

/s/ *Kaspar J. Stoffelmayr* (consent)
Kaspar J. Stoffelmayr
Brian C. Swanson
Katherine M. Swift
Sharon Desh
Sten A. Jernudd
BARTLIT BECK LLP
54 West Hubbard Street
Chicago, Illinois 60654
Phone: (312) 494-4400
E-mail: kaspar.stoffelmayr@bartlitbeck.com
E-mail: brian.swanson@bartlitbeck.com
E-mail: kate.swift@bartlitbeck.com
E-mail: sharon.desh@bartlitbeck.com
E-mail: sten.jernudd@bartlitbeck.com

Alex J. Harris
BARTLIT BECK LLP
1801 Wewatta Street, Suite 1200
Denver, Colorado 80202
Phone: (303) 592-3100
E-mail: alex.harris@bartlitbeck.com

Attorneys for Walgreens Boots Alliance, Inc., Walgreen Co., and Walgreen Eastern Co., Inc.

/s/ *John M. Majoras* (consent)
John M. Majoras
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
Phone: (202) 879-3939
Email: jmmajoras@jonesday.com

Tina M. Tabacchi
Tara A. Fumerton
JONES DAY
77 West Wacker
Chicago, IL 60601
Phone: (312) 269-4335
E-mail: tmtabacchi@jonesday.com
E-mail: tfumerton@jonesday.com

Attorneys for Walmart Inc.

/s/ *Robert M. Barnes* (consent)

Robert M. Barnes
Scott D. Livingston
Joshua A. Kobrin
MARCUS & SHAPIRA LLP
35th Floor, One Oxford Centre 301 Grant Street
Pittsburgh, PA 15219
Phone: (412) 471-3490
Email: rbarnes@marcus-shapira.com
Email: livingston@marcus-shapira.com
Email: kobrin@marcus-shapira.com

Attorneys for Giant Eagle, Inc. and HBC Service Company

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via email to all counsel of record, the Court, and Special Master Cohen on August 27, 2021.

/s/ Eric R. Delinsky
Eric. R. Delinsky